

§ 203.70

and authentication requirements described in paragraph (c) of this section are followed. Where a required document is created on paper and electronically scanned into a computer, the resulting record is an electronic record that must meet the requirements of part 11 of this chapter.

(c) *Security and authentication requirements for request and receipt forms, reports, records, and other documents created on paper.* A request or receipt form, report, record, or other document, and any signature appearing thereon, that is created on paper and that is maintained by photographic imaging, or transmitted electronically (i.e., by facsimile) shall be maintained or transmitted in a form that provides reasonable assurance of being:

(1) Resistant to tampering, revision, modification, fraud, unauthorized use, or alteration;

(2) Preserved in accessible and retrievable fashion; and

(3) Available to permit copying for purposes of review, analysis, verification, authentication, and reproduction by the person who executed the form or created the record, by the manufacturer or distributor, and by authorized personnel of FDA and other regulatory and law enforcement agencies.

(d) *Retention of request and receipt forms, reports, lists, records, and other documents.* Any person required to create or maintain reports, lists, or other records under PDMA, PDA, or this part, including records relating to the distribution of drug samples, shall retain them for at least 3 years after the date of their creation.

(e) *Availability of request and receipt forms, reports, lists, and records.* Any person required to create or maintain request and receipt forms, reports, lists, or other records under PDMA, PDA, or this part shall make them available, upon request, in a form that permits copying or other means of duplication, to FDA or other Federal, State, or local regulatory and law enforcement officials for review and reproduction. The records shall be made available within 2 business days of a request.

21 CFR Ch. I (4–1–02 Edition)

Subpart G—Rewards

§ 203.70 Application for a reward.

(a) *Reward for providing information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample.* A person who provides information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample, or the offer to sell, purchase, or trade a drug sample, in violation of section 503(c)(1) of the act, is entitled to one-half the criminal fine imposed and collected for such violation, but not more than \$125,000.

(b) *Procedure for making application for a reward for providing information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample.* A person who provides information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample, or the offer to sell, purchase, or trade a drug sample, in violation of section 503(c)(1) of the act, may apply for a reward by making written application to:

(1) Director, Office of Compliance (HFD-300), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; or

(2) Director, Office of Compliance and Biologics Quality (HFM-600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, as appropriate.

PART 205—GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

Sec.

205.1 Scope.

205.2 Purpose.

205.3 Definitions.

205.4 Wholesale drug distributor licensing requirement.

205.5 Minimum required information for licensure.

205.6 Minimum qualifications.

205.7 Personnel.

205.8 Violations and penalties.